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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Rose

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EXAMINER

PEPITONE, MICHAEL F

ART UNIT

PAPER NUMBER

1796

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,029	Applicant(s) ROSE, JOHN	
	Examiner MICHAEL PEPITONE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-32, 35-53 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-32, 35-53 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 11-12, 17-21, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Gogolewski *et al.* (US 5,527,341).

Regarding claims 1-4, 11-12, 17-21: Gogolewski *et al.* teaches a membrane (2:30-42) comprising a resorbable poly(DL-lactide co-glycolide) copolymer [instant claims 2-4, 17-21] (2:48-59); wherein the membrane has a Young's modulus of 1 to 50 GPa and a tensile strength of 0.1 to 20 GPa [instant claims 1, 11-12] (2:38-42).

Regarding claims 25-27: Gogolewski *et al.* teaches bioceramics [instant claims 25-27] (3:19-26).

Regarding claims 28-29: Gogolewski *et al.* teaches an implantable device for attachment to tendons and/or reinforcing bones [instant claims 28-29] (2:23-29).

Claims 1-8, 11-12, 17-32, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuan *et al.* (US 6,303,697).

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Regarding claims 1, 3-8, and 11-12: Yuan *et al.* teaches a biocompatible polymeric composite (1:7-12; 3:60-4:8) comprising a copolymer containing from about 50 to about 100 mol% glycolide {glycolic acid} and lactide {lactic acid, racemic D,L-lactide} [instant claims 1, 3-8] (7:48-8:6), with a 10/90 polylactide-co-glycolide (PLA/PGA) copolymer (10:6-25) as a preferred embodiment having a tensile strength of 143.9 ksi {about 992 MPa} ; and a tensile modulus of 2100 ksi {about 14.5 GPa} (11:15-30), and 1.83 E 10 Pa {18.3 GPa}, measured using a DMA {dynamic mechanical analyzer} (11:55-12:18).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and it was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a tensile strength of at least 1100 MPa [instant claim 1] and a tensile modulus of at least 22 GPa [instant claims 1, 11-12], would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claim 2: Yuan *et al.* teaches copolymers of glycolide and lactide copolymerized with ϵ -caprolactone (8:1-6).

Regarding claims 17-21: Yuan *et al.* teaches a composite comprising drawn {strengthened} PLA/PGA fibers [instant claim 17] (10:40-50) and a bioabsorbable polymer matrix {poly-caprolactone} [instant claims 18, 20-21] (8:33-45), wherein a prepreg is formed comprising a volume fraction of 45-50% [instant claim 19] (13:43-57).

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Regarding claims 22-23: Yuan *et al.* teaches a composite comprising biostable polymers [instant claim 22], such as polypropylene [instant claim 23] (6:57-7:18).

Regarding claims 24-27: Yuan *et al.* teaches bone regenerating growth factors [instant claims 24-27] (9:26-39).

Regarding claims 28-29: Yuan *et al.* teaches orthopedic devices {joint replacement prosthesis} [instant claims 28-29] (9:19-25).

Regarding claims 30-32, and 35-37: Yuan *et al.* teaches a method of manufacturing a polymeric composite comprising impregnating polymeric biocompatible fibers (PLA/PGA copolymer) (10:6-67) {which were subjected to a drawing procedure} with a matrix material, wherein the matrix material is a solution of polycaprolactone {formation of a prepreg}, and consolidating the perform using a compression molder, [instant claims 30-32, 35-37] (5:15-36; 5:56-67; 9:40-45; 9:65-67) to afford a composite with no voids, uniform fiber distribution and superior composite properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16, 38-53 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan *et al.* (US 6,303,697) as applied to claim 1 above, and further in view of Jamiolkowski *et al.* (US 4,700,704).

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Regarding claims 13: Yuan *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the polymer composition is formed into a fiber comprising a PLA/PGA copolymer, and subjecting the fibers to a drawing procedure (7:19-47; 10:6-47).

Yuan *et al.* does not teach quenching the fibers after extrusion [instant claim 13]. However, Jamiolkowski *et al.* teaches a polymeric composition comprising copolymers of glycolide and caprolactone (1:10-16), wherein the copolymer is melt spun and extruded into a quench bath {ice water} prior to drawing [instant claim 13] (9:44-55). Yuan *et al.* and Jamiolkowski *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of fibers of glycolide copolymers. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined a quench bath, as taught by Jamiolkowski *et al.* in the invention of Yuan *et al.*, and would have been motivated to do so since Jamiolkowski *et al.* suggests that such glycolide copolymer monofilaments prepared with a quench bath provide synthetic surgical articles having desirable tensile strength, controllable absorbability, and suitable in vivo strengths (2:23-33).

Regarding claim 14: Yuan *et al.* teaches melt extrusion (10:14-25).

Regarding claim 15: Yuan *et al.* teaches a drawing process having the feed rolls at 88 °C and draw rolls at 110 °C {zone heating} (10:40-47).

Regarding claim 16: Yuan *et al.* teaches drawing steps performed under different conditions (7:24-35; 10:14-47).

Regarding claims 38-42: Yuan *et al.* teaches a composite comprising drawn {strengthened} PLA/PGA fibers [instant claims 38] (10:40-50) and a bioabsorbable polymer

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matrix {poly-caprolactone} [instant claims 39, 41-42] (8:33-45), wherein a prepreg is formed comprising a volume fraction of 45-50% instant claim 40] (13:43-57).

Regarding claims 43-44: Yuan *et al.* teaches a composite comprising biostable polymers [instant claim 43], such as polypropylene [instant claim 44] (6:57-7:18).

Regarding claims 45-48: Yuan *et al.* teaches bone regenerating growth factors [instant claims 45-48] (9:26-39).

Regarding claims 49-50: Yuan *et al.* teaches orthopedic devices {joint replacement prosthesis} [instant claims 49-50] (9:19-25).

Regarding claims 51-53 and 56-58: Yuan *et al.* teaches a method of manufacturing a polymeric composite comprising impregnating polymeric biocompatible fibers (PLA/PGA copolymer) (10:6-67) {which were subjected to a drawing procedure} with a matrix material, wherein the matrix material is a solution of polycaprolactone {formation of a prepreg}, and consolidating the perform using a compression molder, [instant claims 51-53, 56-58] (5:15-36; 5:56-67; 9:40-45; 9:65-67) to afford a composite with no voids, uniform fiber distribution and superior composite properties.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan *et al.* (US 6,303,697) in view of Jamiolkowski *et al.* (US 4,700,704), as applied to claim 13 above, and further in view of Okuzaki *et al.* (*Journal of Polymer Science: Part B: Polymer Physics* **1999**, 37, 991-996).

Regarding claim 15: Yuan *et al.* and Jamiolkowski *et al.* renders the basic claimed process obvious [as set forth above with respect to claim 13].

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Yuan *et al.* does not teach zone-heating [instant claim 15]. However, Okuzaki *et al.* teaches zone drawing of PLLA fibers [instant claim 15] (pg. 991). Yuan *et al.* and Okuzaki *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of fibers of biosorbable copolymers. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined zone drawing, as taught by Okuzaki *et al.* in the invention of Yuan *et al.*, and would have been motivated to do so since Okuzaki *et al.* suggests that such zone drawing affords fibers having high orientation with minimal thermal degradation or oxidation occurring (pg. 991).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11-32, 35-53, and 56-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-32 of U.S. Patent No.

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7,455,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed PGA composition having tensile strength of at least 1200 MPa and a tensile modulus of at least 22 GPa overlap in scope. The process of producing the PGA based composition including forming fibers, quenching the fibers, and drawing the fibers under zone heating overlap in scope. Artifacts produced from PGA and non-biosorbable polymer overlap in scope.

Response to Arguments

Applicant's arguments with respect to claims 1-58 have been considered but are moot in view of the new ground(s) of rejection.

Yuan *et al.* (US 6,303,697) discloses the modulus of a 10/90 PLA/PGA fiber to be 1.83 E 10 Pa {18.3 GPa}, measured using a DMA {dynamic mechanical analyzer} (11:55-12:18).

Yuan *et al.* (US '697) also discloses tensile modulus and tensile strength of 14.5 GPa and 992 MPa, respectively {Table 2}, however, it is unclear how these measurements were obtained.

While these numerical values are different from the claimed values {instant claim 1}, one having ordinary skill in the art understands that test protocol, as well as which technique used to obtain tensile properties, will yield different numerical values, even if an identical sample was employed in each measurement. For example, the instant specification {paragraph numbers from PG-PUB} discloses an Instron 5566 machine with a 100 N load cell was employed to determine the tensile properties (§ 42). However, it is unclear of the parameters used during the tensile testing. For example, the temperature of the test and the crosshead speed of the Instron {i.e. the standard used to conduct the measurement} were not indicated. Evidence would need to

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be presented to support applicant's position that the 10/90 PLA/PGA fibers of example 1 disclosed in Yuan *et al.* (US '697) (10:6-67), when tested under similar conditions {on an Instron 5566 machine with a 100 N load cell (§ 42)} would yield tensile data below the claimed values.

Jamiolkowski *et al.* (US 4,700,704) was relied on for quenching melt spun copolymers of glycolide and caprolactone via extrusion into a quench bath {ice water} prior to drawing [instant claim 13] (1:10-16; 9:44-55).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jamiolkowski *et al.* (US '704) suggests that glycolide copolymer monofilaments prepared with a quench bath provide synthetic surgical articles having desirable tensile strength, controllable absorbability, and suitable in vivo strengths (2:23-33).

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Okuzaki *et al.* (*Journal of Polymer Science: Part B: Polymer Physics* **1999**, 37, 991-996) was relied on for zone drawing of biosorbable polymers {PLLA fibers} (pg. 991).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796

MFP
23-January-09